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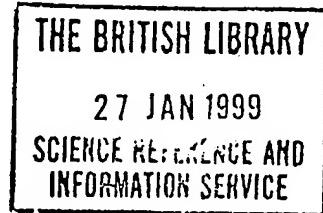
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IN THE MATTER OF EUROPEAN APPLICATION

EP-Application No.: 95 903 212.9

in the name of: C.A. Greiner & Söhne

Gesellschaft m.b.H.

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DECLARATION

I, Sally Sunkel, certified translator, of 4 Saxon Close, Harpenden, Hertfordshire AL5 5HT, England, do hereby declare that I am conversant with the English and German languages and am a competent translator thereof. I further declare that to the best of my knowledge and belief the following is a true and correct translation of the text of the description and claims of the above European Application.

Signed this ...../0<sup>th</sup>..... day of December 1998

.....(Sunkel).....

The invention concerns a collecting device as described in the introductory part of patent claim 1.

A transport system for the dispatch of biological samples has become known according to EP-A1-0 466 009, in which a first container can be inserted in another container and the latter is positioned in the longitudinal direction in the sealed bottom region by means of projecting ribs. Further positioning as well as sealing closure take place by means of a sealing cap in the region of the open ends of the two containers. Between the outer surface of the first container and the inner surface of the second container is arranged a gap which extends all round and over the whole length of the first container. Further, the first container is made of a gas-permeable material and the second container of a gas-tight material. With this embodiment large gaps for containing ambient air are arranged between the two containers and in the bottom region thereof.

From US-A-4,830,217 is known a blood collecting device in which a glass container is surrounded by a plastic container at least over part of its longitudinal extent. The glass container in its sealed end region is positioned within the plastic container by means of symmetrically arranged ribs. The glass container in the region of its open end projects beyond the end edge of the outer plastic container. In the region of the end edge of the plastic container is arranged an additional positioning element which holds the glass container both in the longitudinal direction and radially thereto in relation to the plastic container. Between the two containers is arranged a free space extending all round. The open end of the inner glass container is sealed with a sealing plug.

Further, a collecting device, in particular for blood samples - according to EP-A1-0 512 612 - which consists of a holding container, is already known. This holding container is wrapped with a protective layer which is attached to the holding container. The protective layer is a laminate and transparent, so that the contents of the holding container are visible to an observer from the outside. Identification information may also be printed or indicated on this protective layer. The protective layer prevents the penetration of gas or water vapour, both in the direction of the

holding container and from the holding container to the outside. The application of this protective layer which is formed by a film, for example, requires an additional operation usually after evacuation and sealing of the blood sample tube, and needs exact additional quality control to ensure that on the one hand seamless sheathing of the holding container is achieved and on the other hand snug fitting of the film against the outer surface of the holding container takes place in order to obtain gas-tightness and water vapour-tightness.

It is the object of the present invention to provide a collecting device for liquids, in particular for blood, which is easy to make and exhibits high gas-tightness and water vapour-tightness.

This object is achieved by the characteristics of patent claim 1. The advantage with this solution is that now there are two industrially prefabricated containers which can be assembled by an ordinary joining process and hence the container which holds the liquid is surrounded over the whole of its outer surface seamlessly by the gas-tight and water vapour-tight outer housing. Thus diffusion of gas or air in or out in the longitudinal direction of the holding container between the container and the outer housing is prevented. As a result, the manufacture of such a collecting device for blood is simplified, and also in a surprisingly simple unforeseeable manner the fracture resistance thereof is increased and a safe outer layer is provided which cannot easily be destroyed even with sharp objects. Due to the elimination of an adhesive layer between the container and the outer housing; furthermore, in an advantageous manner solvent vapours or constituents of the adhesive layer are prevented from evaporating out and diffusing into the interior of the container, as a result of which the risk of contamination of the contents in the container is greatly reduced. Due to close fitting of the container against the outer housing, a cavity which might lead to a reduction of the vacuum in the container due to diffusion or on account of the high permeability of the container to gases, is avoided as well. Due to the provision of a press fit between the container and the outer housing, reliable mounting and positioning and air-tight sealing between the container and the outer housing are ensured as well. In addition, by this means support of the

container in the outer housing can easily be obtained by adhesion or by jamming of the container in the outer housing, and the displacement of unwanted residual air within the outer housing can be avoided.

In the development according to patent claim 2 it is an advantage that, due to the at least partly conical design of the outer housing and container, exact positioning of the container in the outer housing can be achieved by means of these cones, and no additional measures are necessary for centring or correct positioning of the container in the outer housing.

If the inner and outer cones have a cone angle according to patent claim 3, then snug fitting of the outer surface of the container against the inner surface of the outer housing is possible too.

An embodiment according to patent claim 4 is advantageous because by this means the two containers can be brought into contact with each other practically over their whole length, and so a dead volume which by pressure equalisation may lead to a reduction of the vacuum in the interior of the container is reduced.

As a result of the embodiment according to patent claim 5, the container can fit snugly in the outer housing even in the region of the sealed end, and the formation of a dead volume in the end region is prevented.

But an embodiment according to patent claim 6 is also an advantage because, even in case of tolerance fluctuations in the diameter of the container and outer housing, it is ensured that the container can be pressed into the outer housing.

A firm fit of the container in the outer housing is ensured by the development according to patent claim 7.

Further, an embodiment according to patent claim 8 is possible too, because by this means mechanical handling when inserting the container in the outer housing is made easier.

By the development according to patent claim 9, the advantages according to the invention can be utilised to a large extent irrespective of the material of the container.

The advantages of composite or sandwich construction technology can also be used by an embodiment according to patent claim 10 for manufacture of the outer housing and container.

Also of advantage is an embodiment according to patent claim 11, because by this means, in addition to ease of manufacture, extraction of air from the outer housing can be obtained irrespective of the assembly position during insertion of the container in the outer housing, without weakening or deformation of the container by groove-like depressions or passages being necessary.

Also advantageous is an embodiment according to patent claim 12, because by this means even in the region of the end wall, fitting of the container against the inner surface of the outer housing almost without play can be achieved.

By the development according to patent claim 12, extraction of the air compressed between the two end regions on insertion of the container in the outer housing until eventually firm fitting of the container in the outer housing can be achieved.

But also advantageous is a development according to patent claim 14, because by this means circulation of the air from one side of the container to the other using the groove-like depressions can be prevented, as a result of which reduction of the vacuum inside the container by permeation, sorption or desorption is prevented.

Another embodiment is described by patent claim 15, as a result of which the circulation cross-section in the depression is reduced, but on the other hand air extraction on insertion of the container in the outer housing can be obtained almost as far as the foremost end region of the ball cup.

An embodiment according to patent claim 16 is possible too, because then due to the increased air permeability in the region of the end wall on insertion of the container in the outer housing the air which is compressed in the process can be extracted through the interior of the container and so the build-up of an air bubble between the two end walls can be prevented.

Also advantageous is another embodiment according to patent claim 17, because by this means the escape of liquid and diffusion of water vapour into any existing cavity between container and outer housing can be prevented.

By the embodiment of the container according to patent claim 18, sufficient liquid-tightness and safe handling of the container are achieved.

By using the gas-tight material according to patent claim 19, diffusion by sorption or permeation of gases or vapours from the outside into the interior of the container is also prevented.

Further, it is also an advantage to develop the collecting device according to patent claim 20, because by this means sufficient fracture resistance can be obtained and, owing to the possible wall thicknesses, a plurality of materials which exhibit sufficient gas-tightness can be used as well.

As a result of the embodiment according to patent claim 21, even in case of high gas permeability or water vapour permeability of the container, a high vacuum can be maintained in the interior thereof over a long period, because penetration of the gas by sorption or desorption or permeation through the outer housing is prevented.

Also advantageous is an embodiment according to patent claim 22, because by this means, in addition to excluding a dead volume between container and outer housing, at the same time firm support of the container in the outer housing is possible without additional measures or steps.

If the embodiment according to patent claim 23 takes place, even with lower wall thicknesses additional reinforcement of the container or outer housing can be achieved by the components needed for air extraction on insertion of the container in the outer housing, wherein for example arrangement of the ribs spirally or in the manner of a thread turn is possible too, in order thus to obtain a high increase in strength of the container or outer housing.

Also advantageous is the development according to patent claim 24, because by this means the rough volume in the depressions can be kept small.

An embodiment of the depressions which is favourable with respect to strength is achieved by characteristics according to patent claim 25.

The development according to patent claim 26 allows universal adaptation of the shape of the air extraction openings to different designs of the outer housing or container.

Further advantageous is an embodiment of the container and/or outer housing according to patent claim 27, because by this means the centrifugal state or contents of the container can easily be checked optically.

The development according to patent claim 28 or 29 allows gas-tight sealing of both the interior of the container and any dead space between the container and the outer housing, so that gas or air which has diffused from the container into the outer housing is sealed off from the outside air and cannot diffuse to the outside, so that an indirect reduction of the vacuum in the container is reliably prevented.

Also advantageous is an embodiment according to patent claim 30, because by this means, with firm fitting of the flange-like attachment against the end of the outer container, tight sealing of both the container and the gap between the container and the outer housing is obtained.

By the development according to patent claim 31 there is obtained a pretensioning sealing device which, even in case of manufacturing tolerances in the container or in the outer container, allows tight sealing thereof from the ambient air.

In addition, by the embodiment according to patent claim 32 it is ensured that, even with simplified insertion of the sealing device, tight sealing of the interior of the container is ensured.

Finally, the embodiments according to patent claims 33 and 34 also describe advantageous developments.

The invention is described in more detail below with the aid of the practical examples shown in the drawings.

They show:

Fig. 1 a collecting device designed according to the invention, e.g. for blood, with an outer housing designed according to the invention and a container in a simplified schematic side view, in section;

Fig. 2 the collecting device in a top view, in section through the lines II-II in Fig. 1;

Fig. 3 the container of the collecting device in a simplified schematic view from below;

Fig. 4 another embodiment of a collecting device in a top view, in section, with webs or ribs arranged on the outer surface of the container and the inner surface of the outer housing;

Fig. 5 another embodiment of a collecting device in a top view, in section, with a container with passages;

Fig. 6 another variant of the collecting device with a container of which the cross-section is not round;

Fig. 7 a collecting device in a side view, in section, and a painted or printed layer with information arranged between the outer housing and the container;

Fig. 8 another embodiment of a collecting device in a simplified schematic side view, in section;

Fig. 9 part of the collecting device according to Fig. 8, in an enlarged side view, in section;

Fig. 10 the collecting device according to Figs. 8 and 9 in a top view and with the sealing device removed.

In Figs. 1 to 3 is shown a collecting device 1 which consists of a cylindrical container 2 and, surrounding the latter, an outer housing 4 acting as a protective layer 3. One end 5 of the outer housing 4 is sealed by an end wall 6 which may be ball cup-shaped, for example, while one end 7 of the outer housing 4 opposite the end 5 is open, but can be sealed with a sealing device 8 which can be removed if need be.

Also the container 2 of the collecting device 1 is sealed at one end 9 by means of an end wall 10 and likewise can be sealed by the sealing device 8 in the opposite end region 11 facing towards the end 7 of the outer housing 4.

Preferred is a length 12 of the outer housing 4 longer by a length difference 13 than a length of the container 2. This length difference 13 usually also corresponds to the length of a sealing surface 14 of a stopper 15 forming the sealing device 8, but can be longer. Preferably the sealing surface 14 overlaps the end region 11 in the longitudinal direction of the container 2 at least slightly.

This stopper 15 is usually clamped in a cap 16 over a flange-like attachment 17 between a peripheral collar 19 resting on an end edge 18 of the outer housing 4, and a retaining washer 20. In order also to achieve gas-tight and liquid-tight sealing of the open end 7 of the outer housing 4 or of the open end region 11 of the container 2, the stopper 15 is formed from a highly elastic and self-sealing material such as e.g. pharmaceutical rubber, silicone rubber or bromobutyl rubber.

For support of the container 2 in the outer housing 4 without play, an inner surface 21 of the outer housing 4 is designed as an inner cone 22 with a cone angle 23, wherein the inner cone 22 tapers from the end edge 18 of the open end 7 of the outer housing 4 in the direction of the end wall 6.

An outer surface 24 of the container 2 on the other hand is provided with an outer cone 25 which preferably has the same or e.g. a slightly larger cone angle 23 as the inner cone 22.

Both the inner cone 22 and the outer cone 25 extend concentrically with a longitudinal axis 26 of the collecting device 1.

In planes 27 and 28 shown schematically by dot and dash lines, a tip diameter 29, for example in the plane 27 of the outer cone 25, corresponds to that of the inner cone 22, or the tip diameter 29 of the outer cone 25 is larger by a slight tolerance, for example between 0.001 mm to 0.2 mm, than the tip diameter 29 of the inner cone 22.

Furthermore, a base diameter 30 of the outer cone and inner cone 22 is preferably the same.

By such a design of the container 2 or outer housing 4, in particular using a cone angle 23 which is between  $4^\circ$  and  $0.2^\circ$ , preferably about  $1^\circ$ , snug telescoping or insertion and positioning of the container 2 and a press fit are possible. Due to the design of the cone angle 23, self-locking between the container 2 and the outer housing 4 can be obtained, or is possible in the outer housing 4.

As can be seen better from Figs. 2 and 3, the container 2 in the region of its outer surface 24 is provided with groove-like depressions 31 which have a depth 32 preferably less than a wall thickness 33 of the container 2, so that the latter comprises a continuously smooth inner surface 34. This wall thickness 33 of the container 2 is between 0.4 mm and 1.2 mm, preferably 0.6 mm to 1.0 mm. The outer housing 4 can also have the wall thicknesses previously mentioned for the container 2.

These groove-like depressions 31 extend from the open end region 11 of the container 2 into the region in which the longitudinal axis 26 intersects with the end wall 10. Preferably, the facing ends 35, 36 of the two groove-like depressions 31

are spaced apart by a distance 37 of between 0.5 mm and 4 mm, and have a depth 32 of between 0.02 mm, and 0.5 mm as well as a width 38 of 0.2 mm to 3 mm, preferably 2 mm. In the view selected here, only two depressions are shown. But it is of course possible to provide any number of depressions there, seen over the circumference.

Preferably, in their ends 35, 36 they taper continuously into the outer surface 24 of the container 2.

The advantage of this interruption or separation of the two groove-like depressions 31 lies in that alternate throughflow of air or gas over the whole outer surface 24 of the container 2 is avoided.

By the depth 32 and width 38 of the groove-like depression 31, however, there is provided such a throughflow cross-section which allows, on insertion of the container 2 in the outer housing 4, the air compressed between the end wall 6 and the end wall 10 to escape in the direction of the open end 7 of the collecting device 1 and from there to emerge into the atmosphere. Thus without considerable compressive stress on the container 2 or outer housing 4, snug fixing or a press fit between the two of them is provided.

Mounting of the container 2 in the outer housing 4, which takes place by a press fit, can also take place or at least be assisted by heating or cooling the outer housing 4 or container 2, so that within the usual temperature range in which such collecting devices are used, a firm press fit is obtained between the container 2 and the outer housing 4. In this case in certain circumstances it is even possible to manage without the groove-like depressions 31 and yet provide problem-free assembly without the formation of a sealed air cushion between the end walls 6 and 10 of the outer housing 4 and container 2.

Due to this solution, in spite of easier assembly, the volume of the cavities required for exit of the air during assembly is kept so small that, even in case of high

permeability of the container to gases, in particular air, and resulting pressure equalisation between the cavity and the interior of the container, an adequate vacuum can still be maintained in the interior of the container over a longer period, in particular the desired storage time.

Usually the pressure in the interior of the container 2 in the unused state ready for operation, that is, evacuated, is between 100 mbars and 800 mbars, so that a vacuum of between 0.2 bar and 0.9 bar is available.

It is further advantageous if the container 2 is made of a liquid-tight, in particular water-tight material, such as e.g. glass, plastic, in particular polypropylene (PP), polyethylene (PE) , high density polyethylene (HDPE) , ABS or the like.

The outer housing 4 and/or the container 2 is resistant to deformation, in particular resistant to elongation, in the direction of the longitudinal axis 26, as a result of which even in case of temperature fluctuations no independent release of the cone connection can occur. A gas-tight material, in particular polyethylene terephthalate (PET), is used as the preferred material for the outer housing. This material has the advantage that it can be made with higher transparency (clear) than a high density polyethylene (HDPE) which can be used similarly. Critical for these materials used for manufacture of the outer housing 4 is that their gas permeability and water vapour permeability are very low. Thus the gas permeability should be less than  $150 \text{ cm}^3/\text{m}^2 \cdot \text{d} \cdot \text{bar}$ , and the water vapour permeability should be less than  $1 \text{ g}/\text{m}^2 \cdot \text{d}$ . These values are obtained for example with polyethylene terephthalate (PET), because at  $23^\circ\text{C}$  the  $\text{g}/\text{M}^2$  water vapour permeability is  $0.6 \text{ g}/\text{m}^2 \cdot \text{d}$  and the gas permeability is  $80/110 \text{ cm}^3 \cdot \text{d} \cdot \text{bar}$ .

For the user of such a collecting device 1 it is particularly advantageous if the container 2 and/or the outer housing 4 is made of a transparent, in particular clear, material, because in this way proper inspection of the interior of the collecting device 1 is ensured, in order to be able to detect satisfactorily the level, for example.

It turned out to be a particularly advantageous choice for the materials of the container 2 as well as of the outer housing 4 if the container 2 is made of liquid-tight material and the outer housing 4 is made of gas-tight material.

In Fig. 4 is shown another embodiment of a collecting device 1 in a top view, in section, the same reference numbers as in Figs. 1 to 3 being used for the same components.

The collecting device 1 again consists of the container 2 supported in the outer housing 4, wherein on the inner surface 21 of the outer housing 4 and on the outer surface 24 of the container 2 are arranged projections 39 in the form of ribs 40 or webs 41. In this embodiment shown here, both on the inner surface 21 and on the outer surface 24 are arranged these projections 39. But it is of course also possible to arrange the projections 39 either only on the inner surface 21 of the outer housing 4 or only on the outer surface 24 of the container 2. It is critical here that the air present on insertion of the container 2 in the outer housing 4 can escape from the interior of the outer housing 4 through channels 42 formed between the projections 39 and so the container 2 can be inserted with its end wall 10 into the region of the end wall 6 of the outer housing 4.

The design and size of the projections 39 or of the channels 42 formed between them must be selected so that on the one hand the air present in the outer housing 4 can escape on insertion of the container 2, but after insertion of the container 2 a secure fit between container 2 and outer housing 4 is ensured. For a better understanding, the projections 39 and channels 42 are shown enlarged not to scale and are between 0.02 mm and 0.5 mm.

The choice of inner and outer cones 22, 25 with the cone angle 23 can correspond to the embodiments already described above, which ensures that there is self-locking in the fitted-together state between the container 2 and the outer housing 4.

It is of course also possible that the outer shape of the container 2 and the inner shape of the outer housing 4 are co-ordinated with each other in such a way that they fit together almost without play, for example with a difference in circumference or diameter of 0.001 mm or the like, in which case fixing of the container 2 in the outer housing 4 can then take place by an adhesive layer, a thermal welding process or the like joining methods.

But of course it is also possible that this difference in diameter or size in the circumferential dimensions between the container 2 and the outer housing 4 is produced by the fact that either the outer housing 4 is heated or the container 2 is cooled to -100°C to -200°C, in order to allow insertion of the container 2 in the outer housing 4 without problems. By this method it is also possible, on account of heating or shrinkage by cooling, to predetermine the latching force or pretensioning force between the container 2 and the outer housing 4, which exists within the range of the usual temperature of use of the collecting device 1.

In Fig. 5 is shown another embodiment of the collecting device 1 in a top view, in section.

The outer housing 4 with its inner surface 21, as shown in the preceding embodiments, also has a round cross-section with a cross-section tapering towards the end wall 6.

The container 2 in this embodiment comprises on its outer surface 24 passages 43 which are in each case offset from each other by about 90° and which again thus form channels 42 between the inner surface 21 of the outer housing 4 and the outer surface 24 of the container 2, for escape of the air from the interior of the outer housing 4.

Between the zones formed by the passages 43 or channels 42 are formed support regions 44 in which the shape of the outer surface 24 of the container 2 is adapted to the shape of the inner surface 21 of the outer housing 4, and these therefore fit together. The outer housing 4 can again be designed with the inner cone 22, and

the container 2 with the outer cone 25, wherein the cone angle 23 can be such that between the inner surface 21 and the outer surface 24 self-locking occurs. The cone angle 23 is then between  $4^\circ$  and  $0.2^\circ$ , preferably  $1^\circ$ . Instead of the continuous conical shape of the container 2 and outer housing 4, it is of course also possible to design these two with a cylindrical longitudinal shape and mount them stationarily one inside the other by projecting clamping or locking lugs. On the other hand it is also possible to make both the container 2 and the outer housing 4 conical only in corresponding parts of their length, so that in these regions mounting and fixing of the container 2 in the outer housing 4 takes place.

The distribution of the passages 43, as seen over the cross-section of the outer surface 24, is here shown only by way of example and can be designed differently, depending on the application or choice of materials, so that instead of the four passages shown in Fig. 5, three or six or any other number can be provided.

In Fig. 6 is shown another variant of the collecting device 1 in cross-section, the same reference numbers again being used for the same components.

The outer housing 4, as already described in the preceding embodiment, again has a round cross-section which can taper in the direction of its end wall 6 by the cone angle 23 or be designed as described above. The container 2 in this embodiment is of oval construction, its outer surface 24 being supported in two diametrically opposed support regions 44 on the inner surface 21 of the outer housing 4. Between the support regions 44 are again formed channels 42 which serve to extract the air from the interior of the outer housing 4. As can further be seen from this view, the container 2 has a maximum length in the direction of an axis between the support regions 44 and a small dimension in an axial direction perpendicular thereto, wherein the difference in dimensions of the container 2 in the axes extending perpendicularly to each other is at least 0.001 mn.

In Fig. 7 is shown another embodiment of the collecting device in a side view, in section, the same reference numbers again being used for the same components.

In this view are shown the different possible arrangements of painted or printed layers 45 between the container 2 and the outer housing 4. The container 2 is again designed at its outer surface 24 with the outer cone 25 tapering in the direction of its end wall 10. On the outer surface 24 on the left of this figure it is shown that a film 46 is arranged there, surrounding the outer surface 24. This film 46 can be designed as a substrate layer 47 for the painted or printed layer 45 and/or as a gas-tight barrier layer. The painted or printed layer 45 may consist of information 48 shown schematically which e.g. indicates to the user of this collecting device 1 different fields of application, if occasion arises additives arranged in the container 2, the expiry date, the partial pressure built up in the interior, manufacturer's information, warnings or, by different colour coding, different spheres of application.

The film 46 applied to the outer surface 24 in this embodiment extends into the region of the plane 27 of the collecting device 1 shown by dot and dash lines.

But it is of course also possible, as shown in the top right region of Fig. 7, to apply the film 46 with the painted or printed layer 45 to the inner surface 21 of the outer housing 4.

In the bottom right region of Fig. 7 it is also shown as an additional variant that the painted or printed layer 45 with its information 48 is introduced without interposition of the film 46 between the outer surface 24 of the container 2 and the inner surface 21 of the outer housing 4. This can take place either by the fact that the painted or printed layer 45 has been applied either to the inner surface 21 or to the outer surface 24 in each case before insertion of the container 2 in the outer housing 4. The painted or printed layer 45 is in this embodiment continuous in the region between the end wall 10 and the end wall 6 over the whole cross-section. In order to allow sufficient air extraction on insertion of the container 2 in the outer housing 4, in this embodiment it is now possible for example to apply the film 46 over two partial regions, so that between the individual film portions, narrow continuous channels 49 are obtained for escape of the air on insertion of the container 2 in the outer housing 4.

Equally it is also possible to interrupt the painted or printed layer 45 applied to the inner surface 21 of the outer housing 4 or the outer surface 24 of the container 2, continuously in the longitudinal direction of the collecting device 1, so that the channels formed thereby can be used to extract air on insertion of the container 2 in the outer housing 4.

Of course it is also possible to arrange the painted or printed layer 45 between two films, that is, in a film sandwich composite, and to apply this film composite to parts or the whole circumference of the container 2 or to the inner surface 21 of the outer housing 4. Attachment of the films 46 and application of the painted or printed layer 45 or corresponding film composites can take place for example by adhesion or integral formation during the process of manufacturing the container 2 and outer housing 4, which usually takes place by injection moulding, in which the painted or printed layer 45 or the film 46 or the composite films are positioned on the mould surfaces of the tools, in order to join them, during the process of manufacturing the container 2 and outer housing 4, directly to them.

In connection with manufacture of the outer housing 4 and/or container 2, instead of manufacturing them by an injection moulding process it is also possible to make them for example by extrusion or by a wrapping process or the like from several lacquers fixed to each other, in each case as a sandwich component, wherein the end walls 6, 10 of the container 2 and outer housing 4 are tightly sealed for example by a thermal shaping process, a blowing process' or the like.

In Figs. 8 to 10 is shown another embodiment of a collecting device 1, the same reference numbers as in Figs. 1 to 7 again being used for the same components.

The collecting device 1 again consists of the inner container 2 which is inserted or pressed into the outer housing 4 designed as a protective layer 3, and supported therein stationarily e.g. by means of a press fit. Both the container 2 and the outer housing 4 are again sealed with end walls 10 and 6 in an end region, that is, the end 9 or the end 5. Further, both the container 2 and the outer housing 4 are open

in the region opposite the end 9 or end 5, that is, the end region 11 as well as the end 7, and can be sealed in this region by means of the sealing device 8.

The sealing device 8 for sealing the open region of the collecting device 1 in turn again consists of the cap 16, the stopper 15 arranged therein and the retaining washer 20. In order to achieve fixing of the stopper 15 in position in the direction of the longitudinal axis 26 in the cap 16, it comprises the attachment 17 which projects radially outwards beyond the sealing surface 14 and extends all round and which is reliably supported on the one hand on the collar 19, which faces towards the end 7 of the outer housing 4 and is connected to the cap 16 in form-locking relationship, and on the other hand on the retaining washer 20 arranged at a distance therefrom in the direction of the longitudinal axis 26. This washer is in turn again fixed in the direction of the longitudinal axis 26 by a bead 50 arranged on the side of the retaining washer 20 opposite the stopper 15 and protruding radially inwards, that is, in the direction of the longitudinal axis 26. The attachment 17 in this case protrudes outwards beyond the sealing surface 14 all round by about the wall thickness of the outer housing 4.

The collar 19 of the cap 16 is supported at the end edge 18 on the sealing device 8 when the latter is fully fitted or screwed on. In order to make it easier to fit or screw the sealing device 8 onto the outer housing 4, on the inside of the cap 16 are shown schematically parts of thread turns 51, 52, 53. These helically arranged thread turns cooperate with web-like or knob-like projections 54 which protrude outwards over the circumference in the region of the end edge 18 of the outer housing 4 and are arranged in certain regions. Thus the whole sealing device 8 and hence also the stopper 15 can be inserted in the open end 7 of the outer housing 4 until an end face 55 of the stopper 15 facing towards the end 5 comes into contact with an end edge 56 of the container 2 in the end region 11 thereof.

As can further be seen from Fig. 8, the outer housing 4 has the length 12, seen the direction of its longitudinal axis 26. The end wall 6 of the outer housing 4 has a thickness 57 in the region of the end 5. Further the end edge 56 of the container 2 is spaced apart by the length difference 13 from the end edge 18 of the outer

housing 4 in the direction of the end wall 6, as a result of which a length 58 arises for the container 2. This length difference 13 is to be kept to exactly, as otherwise there is no sealing contact of the end face 55 of the stopper 15 with the end edge 56 of the container 2, which in this region can then result in ambient air being drawn in through the outer housing 4, and hence the vacuum of the collecting device 1 which has built up in the interior 59 is reduced or the collecting device 1 becomes unusable as a result.

In order now to be able to keep exactly to this length difference 13 between the container 2 and the outer housing 4 over both their lengths 58 and 12 or the thickness 57 of the end wall 6, both the end wall 6 and the end wall 10 have a special design, as can best be seen from Fig. 9. Another problem also arises in the process of manufacturing the container 2 or outer housing 4, as they are made in each case in a separate injection moulding or blowing process, and also the inaccuracies in the region of the sprue of the components must be taken into account. Thus the ball cup-shaped end wall 10 of the container 2 in the region of the longitudinal axis 26 has a passage through 1 the material in the direction of the open end region 11, as a result of which a free space 60 is formed between the outer surface 24 of the container 2 and the inner surface 21 of the outer housing 4. In this free space 60 a sprue 61 for the container 2 is also arranged and shown schematically in the region of the longitudinal axis 26.

In the region of the longitudinal axis 26 the inner surface 21 of the outer housing 4 comprises a projection 62 which is shaped convexly in the direction of the open end 7 and also extends into the free space 60. Further, in dashed lines is shown the ball cup shape of the inner surface 21, to which the thickness 57 of the end wall 6 is also referred.

In the region of the plane 27 which is arranged normally to the longitudinal axis 26 and passes more or less through the centre of the ball cup-shaped end wall 6 or 10, it is indicated that the outer surface 24 of the container 2 forms an offset 63 constantly increasing in the direction of the plane 27, from the inner surface 21 of the outer housing 4. This offset 63 is continuous all round over the whole

circumference and serves on the one hand so that the ball cup-shaped outer surface 24 of the end wall 10 of the container 2, in a region 64 which is arranged centrally to the longitudinal axis 26 and can preferably be approximately between  $60^\circ$  and  $140^\circ$ , fits exactly against the inner surface 21 of the outer housing 4 and on the other hand so that the air remaining in the offset 63 can still be drawn off in the direction of the end region 11 through the depressions 31 distributed over the circumference of the container 2. In this process of extraction or evacuation of the interior 59, the remaining air in the free space 60 is also drawn off via the depressions 31 and the cavity formed by the offset 63. The depressions 31 form the channels 42 which run between the outer surface 24 of the container 2 and the inner surface 21 of the outer housing 4 and extend from the sealed end in the direction of the open end.

Fig. 10 shows a top view of the container 2 and the outer housing 4 with the sealing device 8 lifted off. Here can be seen the depressions 31 arranged on the outer surface 24 of the container 2, which in the present embodiment are offset from each other at an angle of  $120^\circ$ , distributed over the circumference, and extend into the region of the plane 27 and there open out into the cavity formed by the offset 63. As a result, again for assembly of the container 2 with the outer housing 4 it is ensured that the air trapped between the two end walls 6 and 10 can escape through the depressions 31 in the direction of the open end 7, as a result of which satisfactory and easy assembly is ensured. In order to facilitate this assembly process, or due to the process of manufacturing the container 2 and the outer housing 4, these are of conical construction, and both the inner surface 21 of the container 2 comprises the inner cone 22 and the outer surface 24 comprises the outer cone 25, which taper at the cone angle 23 in the direction of the sealed end. The cone angle 23 is here between  $4^\circ$  and  $0.1^\circ$ .

Likewise are shown the projections 54 which are arranged in the region of the end edge 18 and protrude outwardly beyond an outer surface 65 and which cooperate with the thread turns 51 to 53 of the cap 16. The individual projections 54 - in the present embodiment three projections 54 are provided - are offset from each other at an angle of about  $120^\circ$ .

It is again essential in this embodiment that the container 2 is made of a liquid-tight, in particular water-tight, material such as e.g. glass, plastic, such as in particular polypropylene (PP), polyethylene (PE) or the like. A gas-tight material, in particular polyethylene terephthalate (PET), is used as the preferred material for the outer housing 4. A highly elastic and self-sealing material such as e.g. pharmaceutical rubber, silicone rubber or bromobutyl rubber which is both gas-tight and liquid-tight is used as the material for the stopper 15 of the sealing device 8.

Care must further be taken that snug fitting of the end face 55 of the stopper 15 against the end edge 56 of the container 2 is ensured, in order to achieve gas-tight sealing in this region too. For this it is also necessary for both the lengths 12 and 58 to be kept to exactly relative to each other, as a result of which a minor deviation in the length difference 13 also arises.

Finally it should be pointed out that in the embodiments described above, individual parts have been shown disproportionately enlarged in order to improve understanding of the solution according to the invention.

## List of reference numbers

1	collecting device	34	inner surface
2	container	35	end
3	protective layer	36	end
4	outer housing	37	distance
5	end	38	width
6	end wall	39	projection
7	end	40	rib
8	sealing device	41	web
9	end	42	channel
10	end wall	43	passage
11	end region	44	support region
12	length	45	painted or printed layer
13	length difference	46	film
14	sealing surface	47	substrate layer
15	stopper	48	information
16	cap	49	channel
17	attachment	50	bead
18	end edge	51	thread turn
19	collar	52	thread turn
20	retaining washer	53	thread turn
21	inner surface	54	projection
22	inner cone	55	end face
23	cone angle	56	end edge
24	outer surface	57	thickness
25	outer cone	58	length
26	longitudinal axis	59	interior
27	plane	60	free space
28	plane	61	sprue
29	tip diameter	62	projection
30	base diameter	63	offset
31	depression	64	region
32	depth	65	outer surface
33	wall thickness		

## Claims

1. Collecting device for liquids, in particular blood, with a container (2) which is sealed at one end (9) with an end wall (10) and open in its end region (11) opposite the latter, and also with an outer housing (4) which is sealed at one end (5) with an end wall (6) and open at its end (7) opposite the latter, and the container (2) is inserted into the outer housing (4), wherein the container (2) is of liquid-tight construction and the outer housing (4) is of gas-tight construction, characterised in that the container (2) is inserted into the outer housing (4) almost without play and held therein by a press fit, and in that an outer surface (24) of the container (2) fits without play against a main portion of an inner surface (21) of the outer housing (4), and in that between the outer surface (24) of the container (2) and the inner surface (21) of the outer housing (4) is arranged at least one channel (42) which extends from the sealed end (9) or the end (5) in the direction of the open end region (11) or the end (7).
2. Collecting device according to claim 1, characterised in that at least a portion of the inner surface (21) of the outer housing (4) is provided with an inner cone (22) tapering in the direction of an end wall (6), and the container (2) at least in the same partial region as the outer housing comprises an outer cone (25) tapering in the direction of an end wall (10).
3. Collecting device according to claim 2, characterised in that the inner and/or outer cones (22, 25) have the same cone angle (23).
4. Collecting device according to claim 2 or 3, characterised in that the cone angle (23) of the inner and/or outer cone (22, 25) of the container (2) and outer housing (4) is  $0.2^\circ$  to  $4.0^\circ$ , preferably  $1^\circ$ .
5. Collecting device according to one or more of claims 2 to 4, characterised in that a tip diameter (29) of the outer cone (25) in the region of the end (9) sealed by the end wall (10) corresponds to the tip diameter (29) of the inner cone (22) in the region of the end (5) sealed with the end wall (6).

6. Collecting device according to one or more of claims 2 to 4, characterised in that the tip diameter (29) of the inner cone (22) is smaller by at least 0.001 mm than the tip diameter of the outer cone (25) of the container (2).
7. Collecting device according to one or more of claims 1 to 6, characterised in that a length (12) of the outer housing (4) is greater than that of the container (2).
8. Collecting device according to one or more of claims 1 to 7, characterised in that the outer housing (4) and/or the container (2) is resistant to deformation, in particular resistant to elongation, in the direction of the longitudinal axis (26) of the container (2).
9. Collecting device according to one or more of claims 1 to 8, characterised in that the container (2) is made of plastic or glass.
10. Collecting device according to one or more of claims 1 to 9, characterised in that the outer housing (4) and/or the container (2) consists of several layers fixed to each other.
11. Collecting device according to one or more of claims 1 to 10, characterised in that a cross-section in the region of the minimum diameter (29) and in the region of the maximum base diameter (30) has an oval, in particular elliptical cross-section which in an axial direction perpendicular to an axis with maximum length has a dimension at least 0.001 mm smaller.
12. Collecting device according to one or more of claims 1 to 11, characterised in that the end walls (6, 10) are designed to be ball cup-shaped.
13. Collecting device according to one or more of claims 1 to 12, characterised in that in an outer surface (24) of the container (2), in particular between the end

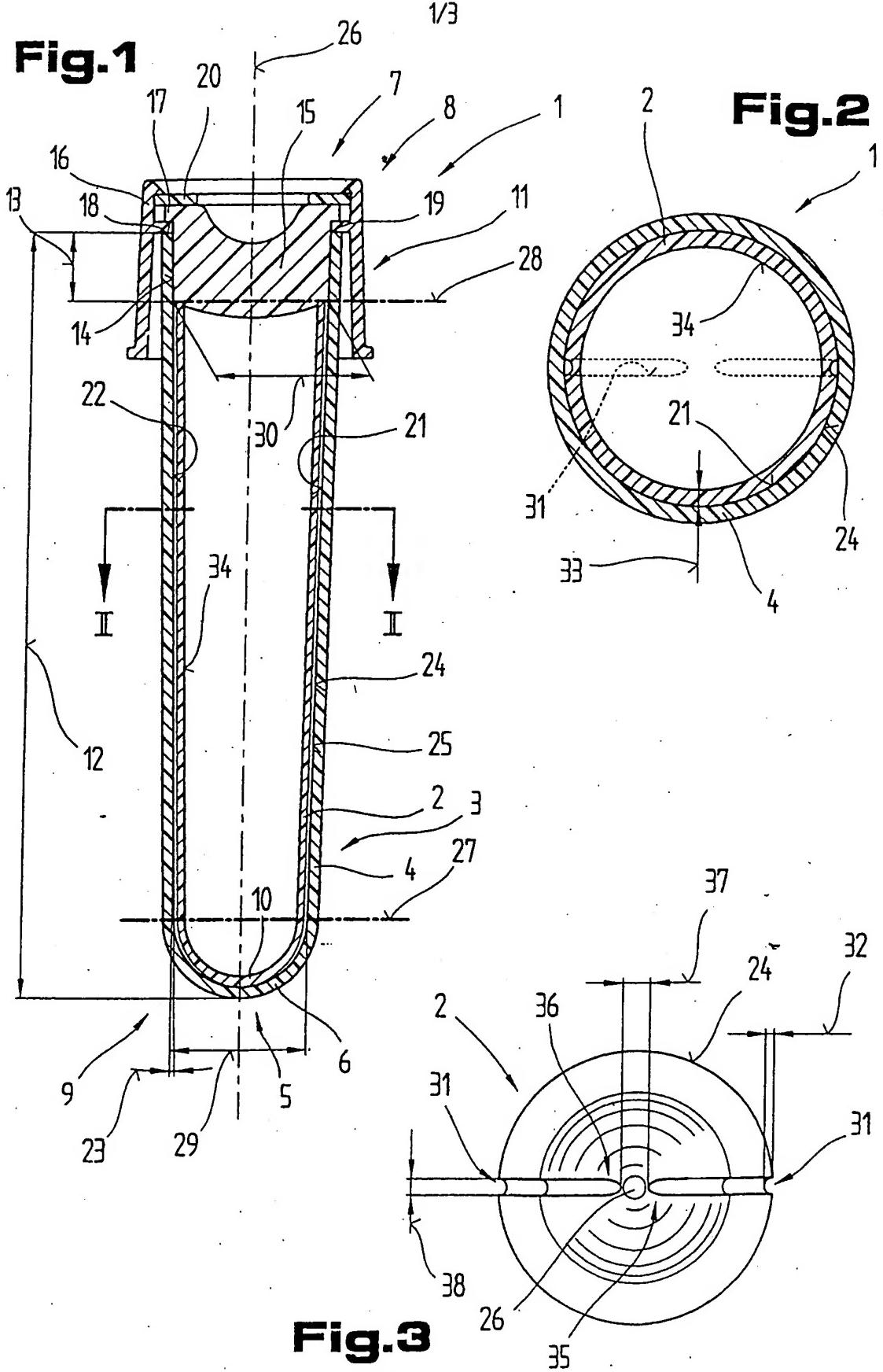
wall (10) and the open end region (11), is arranged a continuous depression (31) designed as a channel (42) with bent depression.

14. Collecting device according to claim 13, characterised in that ends (35, 36) of the groove-like depressions (31) in the region of a point of intersection of a longitudinal axis (26) of the container (2) with the end wall (10) are spaced apart from each other by a distance (37).
15. Collecting device according to claim 13 or 14, characterised in that a groove-like depression (31) in the outer surface (24) of the container (2) runs into the ball cup-shaped end wall (10).
16. Collecting device according to one or more of claims 1 to 15, characterised in that the container (2) at least in the region of the end wall (10) is gas-permeable, in particular air-permeable.
17. Collecting device according to one or more of claims 1 to 16, characterised in that the container (2) is made of a liquid-tight, in particular water-tight material, in particular polypropylene (PP), polyethylene (PE), high density polyethylene (HDPE), ABS or the like.
18. Collecting device according to one or more of claims 1 to 17, characterised in that a wall thickness (33) of the container (2) is between 0.4 mm and 1.2 mm, preferably 0.6 mm to 1 mm.
19. Collecting device according to one or more of claims 1 to 18, characterised in that the outer housing (4) is made of a gas-tight material, in particular a plastic such as e.g. polyethylene terephthalate (PET).
20. Collecting device according to one or more of claims 1 to 19, characterised in that a wall thickness of the outer housing (4) is between 0.4 and 1.2, preferably 0.6 to 1 mm.

21. Collecting device according to one or more of claims 1 to 20, characterised in that material of the outer housing (4) has a water vapour permeability of less than 1 g/m<sup>2</sup>.d and/or a gas permeability of less than 150 cm<sup>3</sup>/m<sup>2</sup>.d.bar.
22. Collecting device according to one or more of claims 2 to 5, characterised in that the outer and inner cones (25, 22) are self-locking.
23. Collecting device according to claim 1, characterised in that on the outer surface (24) of the container (2) and/or on the inner surface (21) of the outer housing (4) are arranged webs (41) or ribs (40) protecting beyond them or the channels (42) are formed between the latter.
24. Collecting device according to one or more of claims 13 to 15, 23 characterised in that a depth (32) of the groove-like depression (31) or the ribs (40) or webs (41) projecting beyond the outer and/or inner surface (24, 21) of the container (2) or outer housing (4) is between 0.02 mm and 0.5 mm.
25. Collecting device according to one or more of claims 13 to 15, 23, 24 characterised in that the container (2) in the region the depressions (31) is provided with passages (43) extending parallel to the longitudinal axis (26).
26. Collecting device according to claim 23 or 24, characterised in that the webs (41) or ribs (40) on the outer surface (24) of the container (2) and/or the inner surface (21) of the outer housing (4) are formed by passages (43) preferably extending parallel to the longitudinal axis (26) of the container (2) or outer housing (4).
27. Collecting device according to one or more of claims 1 to 26, characterised in that the container (2) and/or the outer housing (4) are transparent, preferably glass-clear.
28. Collecting device according to one or more of claims 1 to 27 characterised in that both the open end (7) of the outer housing (4) and the open end region

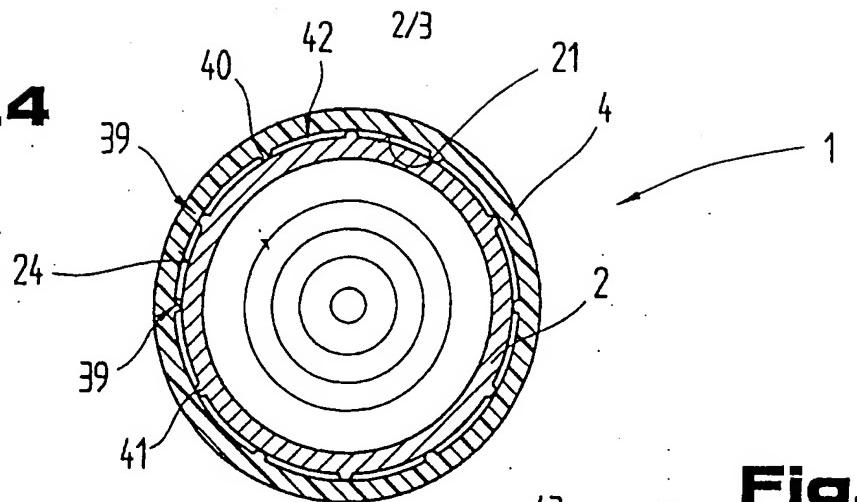
- (11) of the container (2) are sealed by a gas-tight plug (15) of a sealing device (8) and in that the plug (15) projects beyond the end edge (56) of the container (2) in the direction of the end wall (10), and a flange-like attachment (17) projects beyond the inner surface (21) of the outer housing (4) in the direction facing away from the container (2).
29. Collecting device according to claim 28, characterised in that a length of a cylindrical sealing surface (14) of the plug (15) running parallel to the longitudinal axis (26) of the container (2) is greater than a length difference (13) between the lengths of the container (2) and outer housing (4) running parallel the longitudinal axis (26).
30. Collecting device according to claim 28, characterised in that a difference in length parallel to the longitudinal axis (26) of the container (2) between the container (2) and the outer housing (4) is smaller than a length of the cylindrical sealing surface (14) projecting beyond the flange-like attachment parallel to the longitudinal axis (26).
31. Collecting device according to claim 29 or 30, characterised in that a diameter of the cylindrical sealing surface (14) in the slack state is greater than an inside diameter of the container (2) and/or outer housing (4).
32. Collecting device according to one or more of claims 29 to 31, characterised in that the sealing surface (14) tapers preferably conically in the direction opposite that of the flange-like attachment (17), and a diameter of the side facing away from the flange-like attachment (17) is at least slightly greater than an inside diameter of the container (2).
33. Collecting device according to one or more of claims 1 to 32, characterised in that the collecting device (1) serves as a blood sample tube.
34. Collecting device according to one or more of claims 28 to 33, characterised in that an interior (59) of the container (2) is evacuated.

**Fig. 1**

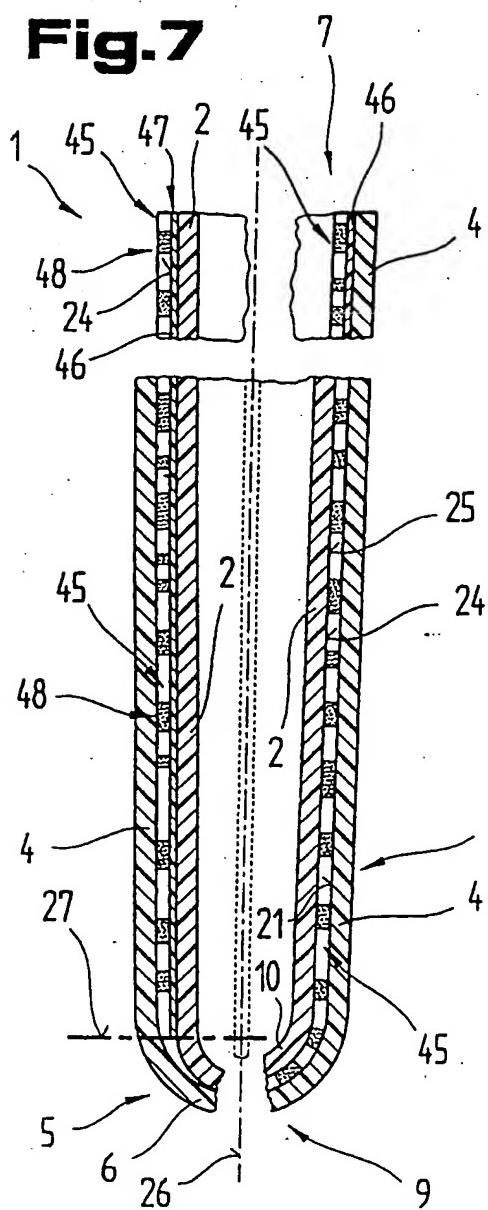


**Fig.2**

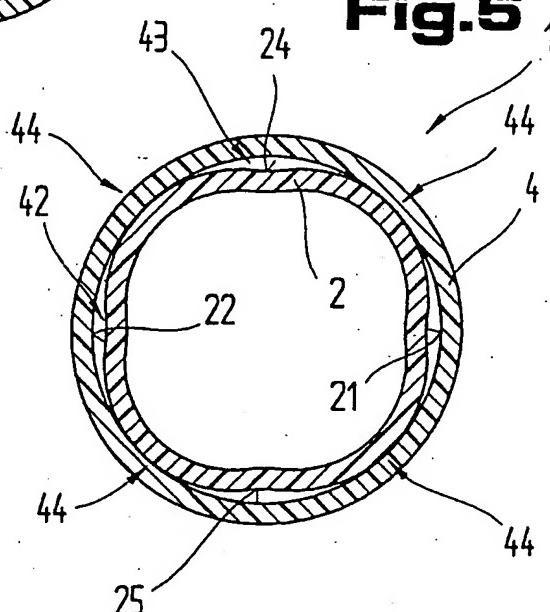
**Fig.4**



**Fig.7**

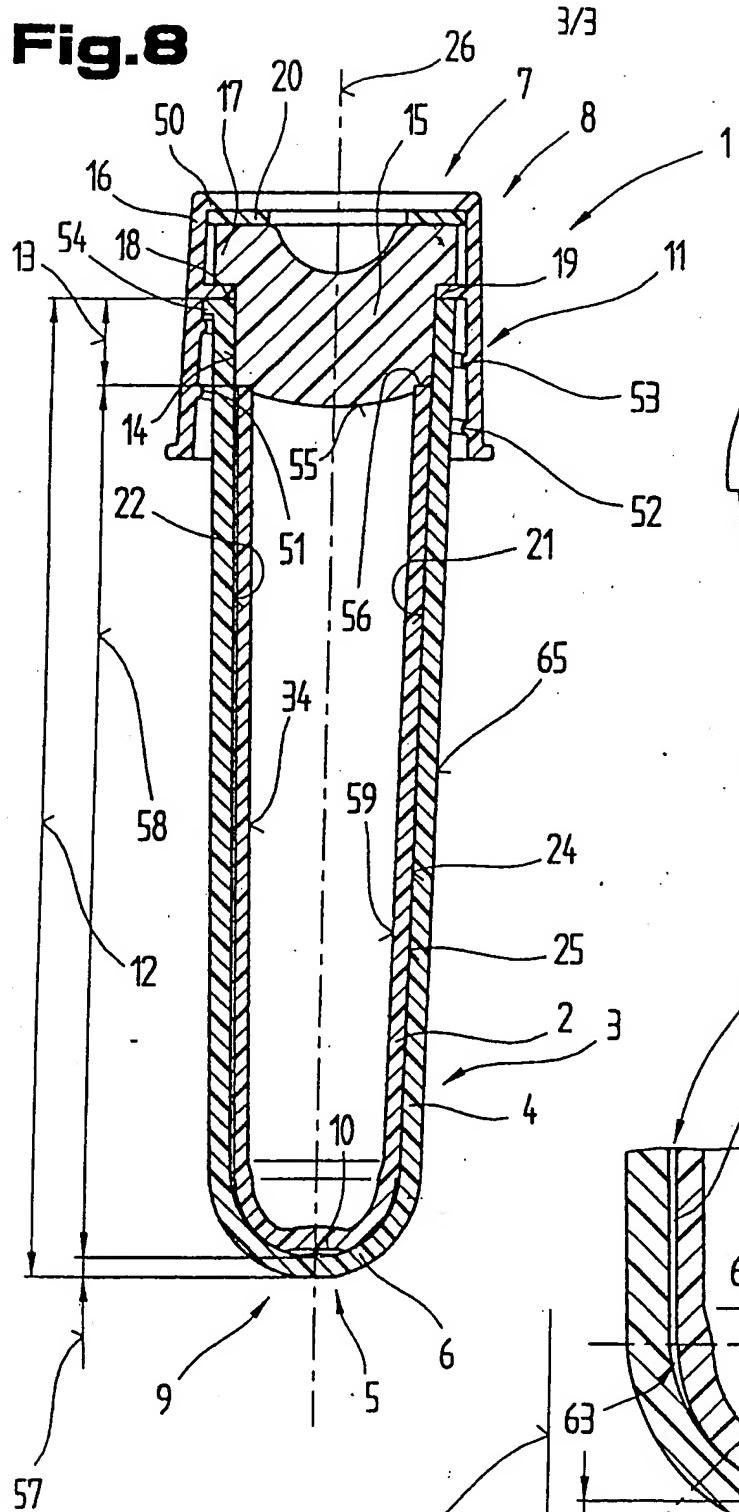


**Fig.5**

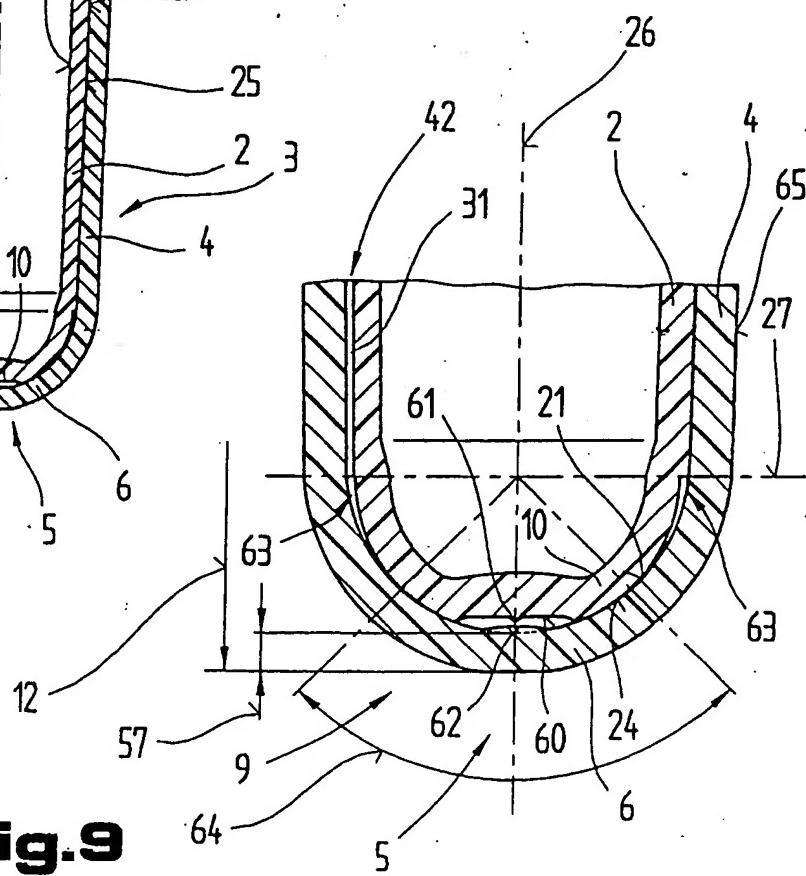


**Fig.6**

**Fig.8**



**Fig.10**



**Fig.9**

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## English title

COLLECTING DEVICE WITH A CYLINDRICAL CONTAINER AND  
BLOOD SAMPLE COLLECTING TUBE USED WITH SUCH A  
COLLECTING DEVICE [1996/41]

## French title

DISPOSITIF DE PRELEVEMENT AVEC UN RECIPIENT CYLINDRIQUE  
ET TUBE DE PRELEVEMENT DE SANG UTILISE AVEC UN TEL  
DISPOSITIF DE PRELEVEMENT [1996/41]

## German title

AUFAHMEVORRICHTUNG MIT EINEM ZYLINDERFÖRMIGEN  
BEHÄLTER UND BLUTPROBENENTNAHMERÖHRCHEN MIT EINER  
DERARTIGEN AUFAHMEVORRICHTUNG [1996/41]

## Designated states, applicant name, address

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04/23-12-1997

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MC/30-06-1999 [2002/26]

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## Blood sample collection container

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Publication date: 1996-05-31  
Inventor(s): KONRAD FRANZ (AT)  
Applicant(s): C A GREINER & S HNE GES M B H (AT)  
Requested Patent:  EP0735921 (WO9517253), B1  
Application Number: CH19950002443 19951221  
Priority Number (s): AT19930002588 19931221; WO1994AT00200 19941221  
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EC Classification: B01L3/14  
Equivalents: AT258893,  AT402365B, AU1216495, AU679303, CA2177974, CN1075962B, CN1137763,  ES2088773, JP9507037T, SG48168,  WO9517253

### Abstract

The collection container (2), such as for blood samples, is cylindrical with an end wall (10) closing one end (9) while the other end is open. A gas impermeable protective layer (3) acts as an outer casing (4) for the container (2). The container (2) is of glass or plastics impermeable to fluid, and especially water, of polypropylene, polyethylene, high density polyethylene, ABS, and the like.

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EP 0735921